

Claims

- 5 1. A method for screening an individual or group of patients for the likelihood of having LVSD comprising, in any order the steps of:
- (a) measurement of the levels of a biomarker in a sample or samples of bodily fluid of said patient; and
- 10 (b) conducting an ECG measurement on said patient or group of individuals; identification of the presence or absence of one or more major abnormality factors from the ECG trace;
- 15 assigning or calculating weighting factors for (a) and (b); and
- obtaining a result indicative of the probability of said individual having LVSD.
- 20 2. A method as claimed in claim 1 comprising the further step performed in any order in relation to the steps of claim 1 of identification of the presence or absence of one or more cofactors which are known to be risk factors for CVD; and assigning or calculating a weighing factor (c) to obtain said result.
- 25 3. A method according to claim 1 or 2 wherein the weighting factors for (a), (b) and/or (c) are derived by logistic regression analysis on measurements of a biomarker, ECG findings, and of one or more cofactors which are known to be risk factors for CVD; wherein the patient population is taken from the general population and individuals have no previous diagnosis of LVSD.
- 30 4. A method according to any of claims 1 to 3 wherein the biomarker is a natriuretic peptide

5. A method according to claim 2 or any claim dependent thereon wherein one or more cofactors are selected from MI and angina.

6. An algorithm for the determination of the likelihood of an individual of having LVSD according to the following formula:

$$\text{Log}_e p/(1-p) = \text{Constant} + B_1*(y) + B_2*(\text{ECG abnormality, a}) +$$

$$B_3*(\text{history of MI or angina, a})$$

where  $p$  is the probability of having heart failure as defined by LVSD;

$B_1$ ,  $B_2$ , and  $B_3$  are the coefficients for the logistic model for predicting LVSD;

Wherein 'a' is a factor to indicate the presence or absence of ECG abnormality and history of MI or angina and wherein 'a' refers to any two numbers sufficiently separated as to impart a different weighting on the coefficients  $B_2$  and  $B_3$  in the presence or absence of ECG abnormality and history of MI or angina.

'y' is either  $\log_{10}$  natriuretic peptide expressed in pM, or peptide centile;

wherein peptide centile, expressed as per cent, is determined by ranking all biomarker levels determined by measuring the biomarker level for an apparently healthy population using a chosen assay kit and expressing them as percentiles.

7. An algorithm for the determination of the likelihood of an individual of having LVSD according to the following formula:

$$\text{Log}_e p/(1-p) = \text{Constant} + B_1*(y) + B_2*(\text{ECG abnormality, a})$$

where  $p$  is the probability of having heart failure due to LVSD

$B_1$  and  $B_2$  are the coefficients for the logistic model for predicting LVSD;

Wherein 'a' is a factor to indicate the presence or absence of ECG abnormality and wherein 'a' refers to any two numbers sufficiently separated as to impart a different weighting on the coefficient  $B_2$  in the presence or absence of ECG abnormality.

'y' is either  $\log_{10}$  natriuretic peptide expressed in pM, or peptide centile;

wherein peptide centile, expressed as per cent, is determined by ranking all biomarker levels determined by measuring the biomarker level for an apparently healthy population using a chosen assay kit and expressing them as percentiles.

8. A method as claimed in any of claims 1 to 5 in which the identification of the presence or absence of one or more major abnormality factors from the ECG trace is determined from the QRS, QT, and/or JT interval.

9. A method as claimed in claim 8 in which the identification of the major abnormality factor is determined from the ratio QRS interval/QT interval or QRS interval/JT interval.

10. A method of deriving an indicator of heart failure in a patient comprising: measuring as a first factor the level of a cardiac bio-marker in a sample of bodily fluid of said patient;

obtaining a patient ECG trace; identifying as a second factor the presence or absence of one or more abnormality factors from the ECG trace; and deriving an indicator of heart failure as a function of the first and second factors.

11. A method as claimed in claim 10 wherein the cardiac bio-marker is a marker indicative of the presence or absence of heart failure.

12. A method as claimed in claim 11 in which the marker is a natriuretic peptide.

13. A method as claimed in claim 12 in which the natriuretic peptide is BNP.

5 14. A method as claimed in any of claims 10 to 13 for deriving an indicator of LVSD.

15. A method of deriving an indicator of heart failure in a patient comprising:

obtaining a patient ECG;

measuring at least one of the QRS, QT and JT interval from the ECG and deriving the

10 indicator of heart failure from the the QRS, JT and/or QT interval.

16. A method as claimed in claim 15 in which the indicator is derived as a function of the ratio QRS interval/QT interval or QRS interval/JT interval.

15 17. A method as claimed in claims 15 or 16 further comprising measuring the level of a bio-marker in a sample of bodily fluid of a patient and deriving the indicator as a function in addition of the measured level.

20 18. An apparatus for measuring an indicator of heart failure in a patient comprising at least one of a QRS interval detector, a QT interval detector and a JT interval detector.

25 19. A heart failure indicator apparatus comprising a data processor arranged to receive data representative of the measurement of a level of a bio-marker in a sample of bodily fluid of a patient and data representing an ECG measurement on the patient and/or data representing a measurement of at least one of a QRS or a QT or a JT interval in an ECG, the processor being further arranged to process the received data to derive an indicator of heart failure.

30 20. A kit of parts comprising at least one of a detector for detecting as a factor levels of a bio-marker in a sample of bodily fluid of a patient, a detector for obtaining an ECG trace from on a patient, a processor for identifying as a factor the presence or

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absence of one or more major abnormality factors from the ECG trace; a processor for measuring as a factor at least one of the QRS, QT and JT interval from an ECG trace and a processor for processing measurements to derive an indicator of heart failure as a function of one or more of the factors.

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21. A computer program comprising a set of instructions configured to implement a method as claimed in any of claims 1 to 5 or 8 to 17.

22. A computer configured to implement a computer program as claimed in claim 21.

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23. A computer readable medium storing a computer program as claimed in claim 21.